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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,800	02/23/2004	Fausto Pinna	249175US0	5473

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EXAMINER	
PETRIK, KARI KRISTEN	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,800	PINNA ET AL.	
	Examiner	Art Unit	
	Kari Petrik	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6,7 and 9-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6,7 and 9-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/28/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*.

DETAILED ACTION

Response to Amendment

1. The amendment filed on 1/04/2006 has been received and made of record. As requested claims 1, 4, 6, 11, 12, 13, 14, and 15 have been amended and claims 16-20 have been added. Claims 1, 3, 4, 6, 7, and 9-20 are currently pending in the application.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 3, 4, 6, 7, 9-16, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,480,717 ("Kundel") in view of U.S. Patent Application Publication 2003/0008011 ("Mershon").

5. As regards claims 1, Kundel discloses hydrogel laminate bandages and composites, thereby disclosing breathable pads (col. 6,lines 14-17), for application to the human skin, to develop a decongestant, cosmetic and/or pharmaceutical action (col. 4, lines 35-40). The pad comprises a flexible porous support (col. 4, lines 62-66) having at least one layer of gel applied to a surface. The support can be woven or nonwoven

fabrics, which are to some extent flexible, porous and breathable. The gel comprises between 50% and 77% of water, between 6.5% and 44% of a dermatologically compatible polymer (col. 4, lines 51-54), between 0% and 10% of a substance of plant origin comprising essential oils and aromatic extracts; and between 0% and 10% of at least one dermatologically compatible component chosen from the group consisting of soothing, skin repairing, cicatrising, anti-inflammatory antiseptic and bactericidal substances, the percentages being by weight.

6. Kundel fails to teach the gel comprises between 0.01% and 5.2% of an alkaline or alkaline earth metal tetraborate, the percentages being by weight. Mershon, however, discloses that it is known to use a tetraborate (borate salts) to thicken (gel) polyvinyl alcohol [0012]. As such, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a tetraborate to the polyvinyl alcohol, when used, in order to thicken or cause the polyvinyl alcohol solution to gel.

7. The applicant should note that the plant origin substance and the dermatologically compatible component do not necessarily have to be present in the prior art in order to meet the claim limitations since they are both present in the range of 0% to 10%.

8. The applicant should also note that auxiliary agents may also be present in the hydrogel, *e.g.,* color stabilizers or coloring agents.

9. As regards claims 3, 4, 6, 7, 9 and10, Kundel fails to explicitly teach the thickness and density of the support (substrate,16), the percent by weight of the

auxiliary agent present in the gel, and the percent by weight of a plant origin substance present in the gel.

The examiner, however, contends that the claims do not appear to contain any additional features, which in combination with the features of any claim to which they refer, add anything novel. As such, absent a critical teaching and/or a showing of unexpected results, the limitations present in claims 3-10 are considered obvious design choices to one having ordinary skill in the art, and the addition of such to a prior art device would have been routine skill in the art.

10. As regards claims 11-12 and 14-15, Kundel fails to explicitly disclose a cosmetic, a decongestant, a decongestant nasal patch or a pharmaceutical eye patch. However, Kundel discloses that medicaments such as an antibacterial agent can be incorporated into the hydrogel. The examiner contends that it would have been obvious to one having ordinary skill in the art at the time the invention was made to add to the hydrogel, decongestants and cosmetics, as well as other pharmaceutical agents for use on the body in order to treat the user. It would also have been obvious to one having ordinary skill in the art at the time the invention was made to place the device on any portion of the body (*i.e.*, eye, nose, hard, chest arm, etc.) needing treatment. It is important to note that when the device is placed on the eye, the device is an eye patch that produces a localized cooling from water evaporating from the gel. Also, when the device comprises a decongestant and it is placed on the nose, it is a nasal patch that exerts a decongestant action.

11. As regards claim 13, the disclosed device of Kundel is a pharmaceutical comprising the breathable pad as outlined in the rejection of claim 1 above.

12. As regards claim 16, 18, and 19, Kundel discloses the breathable pad as outlined in the rejection of claim 1 above. The breathable pad with a gel comprising a dermatologically compatible polymer and a substance of plant origin **or** at least one dermatological compatible component of antiseptic or bactericidal substance (antibacterial agents, column 4, line 40).

Kundel fails to teach the gel comprises between 0.01 wt% and 5.2 wt% of an alkaline or alkaline earth metal tetraborate and the dermatological compatible polymer polyvinyl alcohol. Mershon, however, discloses that it is known to use a tetraborate (borate salts) to thicken (gel) polyvinyl alcohol [0012]. As such, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the pad of Kundel with tetraborate and dermatological compatible polymer (polyvinyl alcohol), as taught by Mershon, thicken the gel.

13. Kundel fails to explicitly teach the percent by weight of the dermatologically compatible component present in the gel. The examiner, however, contends that the claims do not appear to contain any additional features, which in combination with the features of any claim to which they refer, add anything novel. As such, absent a critical teaching and/or a showing of unexpected results, the limitations present in claim 16 are considered obvious design choices to one having ordinary skill in the art, and the addition of such to a prior art device would have been routine skill in the art.

14. As regards to claim 20, Kundel discloses the pad of claim 16 as described above. The breathable pad has a gel layer with water, dermatologically compatible polymer and a dermatologically compatible component wherein the gel is polymerized by electron beam irradiation. Kundel does not teach that the gel is polymerized by gamma rays, beta rays or UV rays. The claimed phrase "wherein the polymerizable components of said gel are polymerized by gamma rays, beta rays or UV rays" is being treated as a product by process limitation; that is, that the gel is polymerized by radiation. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C. 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

Thus, even though Kundel does not disclose the process of polymerization by gamma, beta or UC rays, it appears that the product in Kundel would be the same or similar as that claimed; especially since the prior art's gel has the claimed components.

15. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kundel in view of Mershon as applied to claims 1, 3, 4, 6, 7, 9-16, 18, and 19 above, and further in view of Caskey (US Patent Application 2004/0127826).

Kundel in view of Mershon teach the claimed invention as outlined in the rejection to claim 16 above. Kundel does not disclose that the breathable pad contain 5wt% to 10 wt% of a substance of plant origin. Caskey teaches a breathable (woven or nonwoven) pad having at least one layer of gel (honey, 7 Figure 3) on at least one surface, wherein the gel comprises a substance of plant origin comprising essential oils and aromatic extracts ([0086] and [0103]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the pad of Kundel in view of Mershon, having a substance of plant origin, as taught by Caskey, to provide additional therapeutic properties.

Response to Arguments

16. Applicant's arguments filed 1/4/2006 have been fully considered but they are not persuasive.

17. In response to the applicant's argument that the pad disclosed by Kundel is not breathable and teaches away from a breathable product, the examiner disagrees. Kundel only states that a moisture-impermeable film is preferred. The reference also states that other "suitable substrates include woven or nonwoven fabrics" (column 4, lines64-65), which are flexible, porous and breathable. The woven or nonwoven fabric having a polymeric adhesive would still be breathable because there are many well-known moisture permeable adhesives. Furthermore, Mershon is being used to teach components of the gel not the support, so there is no issue of the reference teaching away from the invention. Therefore, Kundel modified by Mershon does disclose a breathable and porous pad that meets the limitations of the claims.

18. In response to the applicant's argument that Mershon does not complement the elements missing from the primary reference, refer to the rejection of claim 1 above. Mershon teaches the tetraborate and the polyvinyl alcohol, which applicant states is a preferred polymer on page 3 line 14 of the specification.

19. In response to the applicant's argument that the prior art does not disclose the gel of claim 16, refer to the claim rejection above. Kundel discloses at least one dermatologically compatible component, which meets the claim limitation since it does not require both of the substances to be present.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kari Petrik whose telephone number is (571)272-8057. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571)272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KKP
KP

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